K050717

MAY 13 2005

CooperVision

510(k) SUMMARY

1. **Submitter:**

   Submitted on Behalf of:

   - Company Name: CooperVision, Inc.
   - Address: 711 North Road, Scottsville, NY 14546

2. **Official Correspondent:** Bonnie Tsymbal

   - Company Name: CooperVision, Inc.
   - Address: 711 North Road, Scottsville, NY 14546
   - Phone: (585) 264-3210
   - Fax: (585) 889-5688

3. **Date Summary Prepared:** March 17th, 2005

4. **Device Identification:**

   - Trade Name: Proclear UltraVue Toric, Proclear UltraVue Multifocal, Proclear UltraVue 2000T Multifocal Toric (omafilcon A) Soft (hydrophilic) Contact Lenses
   - Common Name: Hydrophilic Soft Contact Lens
   - Classification: Lenses, Soft Contact, Daily Wear 86LPL
   - Device Classification: Class II (21 CFR 886.5925)

5. **Intended Use:**

Proclear UltraVue/D 2000T and Proclear UltraVue/N 2000T Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic, possess astigmatism of 3.00 diopters or less, and are presbyopic. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Proclear UltraVue/D and Proclear UltraVue/N Multifocal (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic and are presbyopic. The lenses may be worn by persons who exhibit astigmatism of 0.75 diopters or less that does not interfere with visual acuity. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Proclear UltraVue Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic, possess astigmatism of 5.00 diopters or less. The lenses may provide improved comfort for contact lens wearers who experience mild discomfort or symptoms related to dryness during lens wear associated with Evaporative Tear Deficiency or from Aqueous Tear Deficiency (non-Sjogren's only).

Daily wear replacement schedules may vary from patient to patient and should be decided by the eye care practitioner in consultation with their patients. The lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.

6. Device Description

Proclear UltraVue Toric

Proclear UltraVue Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are made of polymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The lenses are tinted edge to edge for visibility purposes with the color additive C. I. Reactive Blue 4. Proclear UltraVue Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are available as astigmatic (toric) lenses with the following dimensions:

- Chord Diameter: 13.6 to 15.2 mm
- Center Thickness (minus): 0.15 mm to 0.20 mm
  Center Thickness (plus) 0.20 mm to 0.96 mm
- Base Curve: 8.0 mm to 9.3 mm
- Spherical Powers: -20.00 D to +20.00 D
- Cylinder Powers: -0.75 to –5.00 D
- Axis 1° to 180°

Proclear UltraVue/D Multifocal and Proclear UltraVue/N Multifocal

Proclear UltraVue/D and Proclear UltraVue/N (omafilcon A) Soft (Hydrophilic) Contact Lenses are available as a multifocal lens with an aspherical front surface and spherical back surface for the correction of visual acuity in presbyopic persons who are myopic or hyperopic. The Proclear UltraVue/D and Proclear UltraVue/N is designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength. The Proclear UltraVue/D has a spherical central zone for the correction of distance vision and an aspherical annular zone for the correction of intermediate and near vision. The Proclear UltraVue/N has a spherical central zone for the correction of near vision and an aspherical annular zone for the correction of intermediate and distance vision. The lenses are tinted edge to edge for visibility purposes with the color additive C. I. Reactive Blue 4.

The lens material, omafilcon A is a copolymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The Proclear UltraVue/D and Proclear UltraVue/N (omafilcon A) Soft (Hydrophilic) Contact Lenses are flexible transparent hemispherical shells of the following dimensions:

- Chord Diameter: 14.5 mm
- Center Thickness (minus): 0.15 mm to 0.20 mm
  Center Thickness (plus) 0.20 mm to 0.96 mm
- Base Curve: 8.3 mm to 8.9mm
- Spherical Powers: -20.00 D to +20.00 D
- Add Powers: +1.00 to +4.00 D
- Central Zone Diameter: 2.3 mm to 2.6 mm (Proclear UltraVue/D)
  1.7 mm to 2.0 mm (Proclear UltraVue/N)

Proclear UltraVue/D 2000T Multifocal Toric and Proclear UltraVue/N 2000T Multifocal Toric

Proclear UltraVue/D 2000T and Proclear UltraVue/N 2000T Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are made of polymer of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phosphorylcholine crosslinked with ethyleneglycol dimethacrylate. The lenses are tinted edge to edge for visibility purposes with the color additive C. I. Reactive Blue 4.

The front surface of the Proclear UltraVue/D 2000T and Proclear UltraVue/N 2000T Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses is aspherical, with the anterior surface having a toric generated surface for the purpose of correcting vision in an eye that is astigmatic. The Proclear UltraVue/D 2000T and Proclear UltraVue/N 2000T Multifocal Toric contact lenses are designed with two multifocal zones, as well as the edge shape being optimized to provide comfort without sacrificing tensile strength.

The Proclear UltraVue/D 2000T and Proclear UltraVue/N 2000T Multifocal Toric (omafilcon A) Soft (Hydrophilic) Contact Lenses are available in two versions. The ***Proclear UltraVue/D 2000T*** with a spherical central zone for the correction of distance vision and an aspherical annular zone for the correction of intermediate and near vision. The ***Proclear UltraVue/N 2000T*** with a spherical central zone for the correction of near vision and an aspherical annular zone for the correction of intermediate and distance vision.

Both lenses are a flexible transparent hemispherical shell of the following dimensions:

- Chord Diameter: 14.5 mm
- Center Thickness (minus): 0.15 mm to 0.20 mm
  Center Thickness (plus) 0.20 mm to 0.96 mm
- Base Curve: 8.3 mm to 8.9mm
- Spherical Powers: -20.00 D to +20.00 D
- Cylinder Powers: -0.75 to –2.75 D
- Add Powers: +1.00 to +3.50
- Central Zone Diameter: 2.3 mm to 2.6 mm (Proclear UltraVue/D 2000T)
  1.7 mm to 2.0 mm (Proclear UltraVue/N 2000T)

The physical properties of the lenses are:

Refractive Index at 25^0 C	1.40
Light Transmittance	>90%
Water Content	59 %
Oxygen Permeability*	21.05 x 10^{-11}

**(cm^2/sec) (ml O_2/ml x mm Hg) at 35° C. as measured by 201T Permeometer connected to a curved Rehder guard ring polarographic cell.*

7. Substantial Equivalence Table:

	Proclear Tailor Made Toric, Proclear UltraVue Multifocal Proclear UltraVue 2000T Multifocal Toric *Lathed* *Predicate Device*	**Proclear UltraVue Toric, Proclear UltraVue Multifocal and Proclear UltraVue 2000T Multifocal Toric** *Finished Inside Polymerization System* *Subject Device*
Material	Omafilcon A	Omafilcon A
Water Content	59%	59%
Light Transmittance	>90%	>90%
Index of Refraction	1.40	1.40
Oxygen Permeability	21.05	25.0

DESIGN COMPARISON		
	Proclear UltraVue Toric Subject Device **Omafilcon A**	**Proclear Tailor Made Toric** Predicate Device K952152 **Omafilcon A**
Lens Design	Back Surface Toric	Back Surface Toric
Intended Use	Correction of visual acuity in patients with myopia or hyperopia, and are astigmatic	Correction of visual acuity in patients with myopia or hyperopia, and are astigmatic
Production Method	Finished Inside Polymerization System	Lathe-Cut
	Proclear UltraVue Multifocal Subject Device **Omafilcon A**	**Proclear UltraVue Multifocal** Predicate Device K043129 **Omafilcon A**
Lens Design	Aspheric Multifocal	Aspheric Multifocal
Intended Use	Correction of visual acuity in patients with myopia or hyperopia, and are presbyopic	Correction of visual acuity in patients with myopia or hyperopia, and are presbyopic
Production Method	Finished Inside Polymerization System	Lathe-Cut
	Proclear UltraVue 2000T Multifocal Toric Subject Device **Omafilcon A**	**Proclear UltraVue 2000T Multifocal Toric** Predicate Device K0423129 **Omafilcon A**
Lens Design	Aspheric Multifocal Toric	Aspheric Multifocal Toric
Intended Use	Correction of visual acuity in patients with myopia or hyperopia, and are astigmatic and presbyopic	Correction of visual acuity in patients with myopia or hyperopia, and are astigmatic and presbyopic
Production Method	Finished Inside Polymerization System	Lathe-Cut

8. CONCLUSION:

The device will be manufactured according to specified process controls and an established quality assurance program. The device will undergo the same manufacturing, packaging and sterilization procedures to devices currently marketed by CooperVision, Inc. Scottsville, NY manufacturing facility. Being similar with respect to indications for use, the risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2005

Cooper Vision
c/o Ms. Bonnie Tsymbal
Sr. Manager
Regulatory Affairs and Quality Assurance
711 North Road
Scottsville, NY 14546

Re: K050717
Trade/Device Name:
Proclear UltraVue/D 2000T and Proclear UltraVue/N 2000T Multifocal Toric (omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Proclear UltraVue/D and Proclear UltraVue/N Multifocal (omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Proclear UltraVue Toric (omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 18, 2005
Received: March 24, 2005

Dear Ms. Tsymbal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CooperVision
Regulatory Affairs
711 North Road
Scottsville, NY 14546
(585) 385-6810
Fax: (585) 889-5688

Indication for Use Statement

510(k) Number:

Device Name: Proclear UltraVue/D 2000T and Proclear UltraVue/N 2000T Multifocal Toric (omafilcon A) Soft (hydrophilic) Contact Lens
Proclear UltraVue/D and Proclear UltraVue/N Multifocal (omafilcon A) Soft (hydrophilic) Contact Lens
Proclear UltraVue Toric (omafilcon A) Soft (hydrophilic) Contact Lens

Indication for Use:

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PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K050717

Prescription Use X
(Per 21 CFR Subpart D)

AND/OR

Over-The-Counter ____
(Per 21 CFR Subpart C)